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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,152	04/12/2004	Philip A. Carpino	PC25808A	4558

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
11/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/823,152
Filing Date: April 12, 2004
Appellant(s): CARPINO ET AL.

Arlene K. Musser
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/15/08 appealing from the Office action mailed

8/4/08

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 8/14 /08 was not entered.

It is however being entered now.

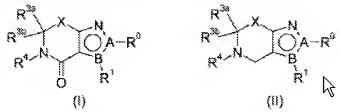
(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by

reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because the applicants have not shown just the elected group but the full invention. This has been restricted and in the response filed 6/30/05 applicants elected group I wherein A is a N and B is a carbon. and X is a bond. The election was made without traverse. The claims were amended and the current pending claims are as filed on 5/7/08.

Claim 1 now reads.

1(previously presented). A compound of Formula (I) or (II)



(I) (II)

wherein

A is nitrogen and B is carbon;

R^0 is a phenyl substituted with 1 to 3 substituents independently selected from the group consisting of halo, $(C_1$-$C_4)$alkoxy, halo-substituted $(C_1$-$C_4)$alkyl, and cyano;

R^1 is a phenyl substituted with 1 to 3 substituents independently selected from the group consisting of halo, $(C_1$-$C_4)$alkoxy, halo-substituted $(C_1$-$C_4)$alkyl, and cyano;

X is a bond;

R^{3a} and R^{3b} are each independently hydrogen, $(C_1$-$C_4)$alkyl, or halo-substituted $(C_1$-$C_4)$alkyl; and

R^4 is $(C_1$-$C_8)$alkyl, halo-substituted $(C_1$-$C_8)$alkyl, cyclopentyl, cyclohexyl, piperidin-1-yl, pyrrolidin-1-yl, or morpholin-4-yl;

provided that when the compound is a compound of Formula (II), R^{3a} and R^{3b} are not both hydrogen.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of the claims under 35 USC 112 first paragraph has been withdrawn.

The general issue on Appeal is whether the Examiner erred in rejecting Claims 1,4, 8-11, 31, 35, 36, 42, 43, 49, 55, 59 and 64 on the ground of non-statutory obviousness-type double patenting over Claims 1-23 of US Patent No. 7,230,024.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

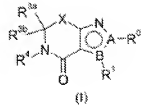
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

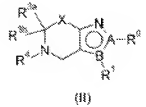
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim1, 4, 8, 9, 10, 31, 35, 36, 42, 43, 49, 55, 59 and 64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-23 of U.S. Patent No. 7, 230,024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structures are very similar and the compounds are isomers and hence prima facie obvious. Please see explanation below.

The claims compounds are drawn to the compounds of the formula



(I)



(II)

wherein

A is nitrogen and B is carbon;

R^{2a} is a phenyl substituted with 1 to 3 substituents independently selected from the group consisting of halo, (C_1-C_4)alkoxy, halo-substituted (C_1-C_4)alkyl, and cyano;

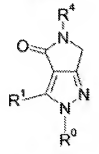
R^1 is a phenyl substituted with 1 to 3 substituents independently selected from the group consisting of halo, (C_1-C_4)alkoxy, halo-substituted (C_1-C_4)alkyl, and cyano;

X is a bond;

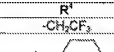
So with X being a bond it makes it a bicyclic ring of two 5 membered ring.

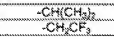
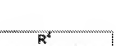
As given on page 48 of their specifications the species disclosed are as follows.

Table 1



Ex. No.	R^0	R^1	R^4	LCMS m/z (M+1)
1A-2	2-chlorophenyl	4-cyanophenyl	isopropyl	377.1
1A-3	2-chlorophenyl	4-chlorophenyl	isopropyl	386.1

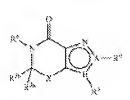
Ex. No.	R^0	R^1	R^4
1A-1P	2-chlorophenyl	4-chlorophenyl	$-CH_2CF_3$
1A-2P	2-chlorophenyl	4-chlorophenyl	
1A-3P	2,4-dichlorophenyl	4-chloro-phenyl	$-CH(CH_3)_2$
1A-4P	2,4-dichlorophenyl	4-chloro-phenyl	$-CH_2CF_3$

Ex. No.	R^0	R^1	R^4
1A-5P	2,4-dichlorophenyl	4-chloro-phenyl	
1A-6P	3-chloro-phenyl	4-chloro-phenyl	$-CH(CH_3)_2$
1A-7P	3-chloro-phenyl	4-chloro-phenyl	$-CH_2CF_3$
1A-8P	3-chloro-phenyl	4-chloro-phenyl	

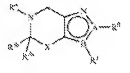
The US 7, 230,024 patent claims are drawn to

1. A compound of Formula (I) or (II)

(I)



(II)



wherein

A is nitrogen and B is carbon,

R^{1a} is an aryl optionally substituted with one or more substituents or a heteroaryl optionally substituted with one or more substituents;

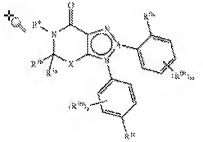
R^1 is aryl optionally substituted with one or more substituents, heteroaryl optionally substituted with one or more substituents, $-CH=CH-R^{1A}$, where R^{1A} is hydrogen or a chemical moiety selected from $(C_1$-$C_4)$ alkyl, 3- to 8-membered partially or fully saturated carbocyclic ring(s), 3- to 8-membered partially or fully saturated heterocycle, aryl, heteroaryl, where the chemical moiety is optionally substituted with one or more substituents;

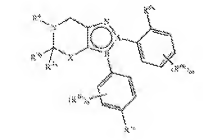
X is a bond;

R^{2a} and R^{2b} are each independently hydrogen, $(C_1$-$C_4)$

Claims 7 is drawn to compounds of the formula

17. A compound of Formula (III) or (IV)

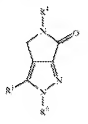




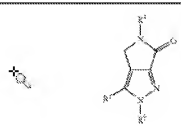
These are all pharmaceutical compounds.
According to the specifications definition the "pharmaceuticals" are used to treat obesity and also act on the same receptor.

The species of claim 8 are given in a structural formula in Table 1 column 46, 47 some of which are reproduced here.

TABLE 1



Ex. No	R^4	R^1	R^6	LCMS m/z (M + 1)+
1A-2	2-chlorophenyl	2-chlorophenyl	···CH(CH$_3$)$_2$	386.3
1A-3	2-chlorophenyl	4-(methoxycarbonyl)phenyl	···CH(CH$_3$)$_2$	394.4

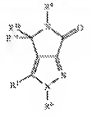


Ex. No.	R^2	R^4	R^5	LCMS m/e ($M+1$)$^+$
1A-4	2-chlorophenyl	2-fluorophenyl	---$CH_2CH_2N_3$	378.3
1A-5	2-chlorophenyl	2-methoxy-pyridyl-5-yl	---CH_2CH_2	387.4
1A-6	2-chlorophenyl	3-chloro-4-fluorophenyl	---CH_2CH_2	404.2
1A-7	2-chlorophenyl	4-fluoro-3-methylphenyl	---CH_2CH_2	390.3
1A-8	2-chlorophenyl	vinyl	---CH_2CH_2	302.3
1A-9	2-chlorophenyl	3-trifluoromethyl-4-phenyl	2,2,2-trifluoroethyl	486.4
1A-10	2-chlorophenyl	4-trifluoromethyl-phenyl	isopropyl	420.4
1A-11	2-chlorophenyl	4-chlorophenyl	ethyl	372.4
1A-12	2-chlorophenyl	2-chlorophenyl	isopropyl	386.3
1A-13	2-chlorophenyl	4-methoxymethyl-phenyl	isopropyl	396.4
1A-14	2-chlorophenyl	2-fluorophenyl	isopropyl	370.3
1A-15	2-chlorophenyl	4-chlorophenyl	2-fluoroethyl	390.3
1A-16	2-chlorophenyl	4-chlorophenyl	2,2-difluoroethyl	408.3
1A-17	2-chlorophenyl	4-chlorophenyl	2,2,2-trifluoroethyl	426.3
1A-18	2-chlorophenyl	4-ethoxyphenyl	n-butyl	416.4
1A-19	2-chlorophenyl	4-chlorophenyl	n-butyl	406.4
1A-20	2-chlorophenyl	4-chlorophenyl	ethyl	382.4
1A-21	2-chlorophenyl	4-ethoxyphenyl	isopropyl	396.4
1A-22	2-chlorophenyl	4-ethoxyphenyl	2,2,2-trifluoroethyl	458.4
1A-23	2-chlorophenyl	4-ethylphenyl	n-butyl	394.5
1A-24	2-chlorophenyl	4-ethylphenyl	n-octyl	394.5
1A-25	2-chlorophenyl	4-ethylphenyl	ethyl	366.4
1A-26	2-chlorophenyl	4-ethylphenyl	isopropyl	380.4
1A-27	2-chlorophenyl	4-ethylphenyl	2,2,2-trifluoroethyl	420.4
1A-28	2-chlorophenyl	4-ethylphenyl	2,2-difluoropropyl	416.5
1A-29	2-chlorophenyl	4-cyclopentylphenyl	n-butyl	434.5
1A-30	2-chlorophenyl	4-isopropylphenyl	n-butyl	408.3
1A-31	2-chlorophenyl	4-isopropoxyphenyl	ethyl	398.3
1A-32	2-chlorophenyl	4-isopropoxyphenyl	isopropyl	412.2
1A-33	2-chlorophenyl	4-isopropylphenyl	2,2,2-trifluoroethyl	452.2
1A-34	2-chlorophenyl	4-isopropylphenyl	2,2-difluoropropyl	448.3
1A-35	2-chlorophenyl	4-n-butylphenyl	2,2,2-trifluoroethyl	468.4
1A-36	2-chlorophenyl	4-n-butylphenyl	2,2-difluoropropyl	464.5

Also see table 3 column 55.

55

TABLE 3-continued

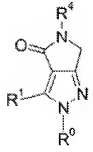


Ex No.	R^2	R^4	R^{2a}	R^{3a}	R^4	+APCI MS (M + 1)
3A-9	4-chlorophenyl	2-chlorophenyl	H	H		386.1
3A-10	4-chlorophenyl	2-chlorophenyl	H	H		412.4
3A-11	4-chlorophenyl	2-chlorophenyl	H	H		426.4
3A-12	4-chlorophenyl	2-chlorophenyl	H	H		438.1
3A-13	4-chlorophenyl	2-fluorophenyl	H	H		390.4
3A-14	4-chlorophenyl	2-bromophenyl	H	H		450.5
3A-15	4-chlorophenyl	2-chlorophenyl	H	H		427.3
3A-16	2-chlorophenyl	2-chlorophenyl	H	H		427.3
3A-17	4-chlorophenyl	2-chlorophenyl	H	H		427.3
3A-18	4-chlorophenyl	2-chlorophenyl	H	H		413.1

Difference between patent and the claims MPEP 2141.02

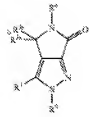
The difference is only in the position of the double bond O group on the core.

For clarity the examiner has shown the species .



Applicants compounds.

US 7, 230,024 's compounds are



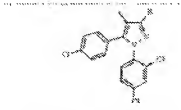
See compound *1A3 of appellants compound and 1A2 of the patent* .

The substituents R1, R0, R4 are the same and appellants do not argue that.

The only difference is the double bond O, =O.
They are on different sides, making the compounds positional isomers.
Making the compounds "4-ones " instead on the patents "6-ones'.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

It should be noted that SR141716A the compound appellants compare the activity of the compound with , given in the specifications and also shown in the office action of 4/16/08 is given by The structure



with R being 

It should be noted that the pyrazole core with the two phenyl rings is the same in the US patent and applicants.

Thus there is a clear teaching that R group or the bicyclic part of the pyrrazole may not effect the activity. These all have cannabinoid receptor activity.

The activity it appears to depend on the pyrazole with the 2 phenyl rings.
Also structurally similar compounds have similar activities.
In re Wilder, 563 F. 2d 457, 195 USPQ 426.

Both applicants compounds and those of the patent have the same pyrazole with the 2 phenyl rings. Thus one of skill in the art would consider that the isomers with the different position of the =O, to also have the same activity, thus motivating a person skilled in the art to try , with a definite amount of predictability of being successful.
According to KSR v Teleflex Inc. 2007 there are several rationales for motivation.
They are given below.

Rationales

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try"—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

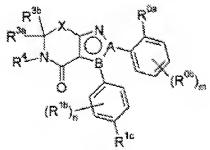
(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

In this case the structure is very similar to that of the known SR 141716 .
The positional difference is in the =0, Thus motivating a person and making it obvious to try for a person of skill in the art to make and use the isomers with =O at a different position , with a predictability of success, and expect the properties and activity to be the same.

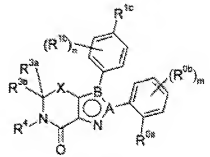
(10) Response to Argument

Appellants argue that

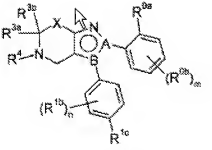
Firstly, the inventive compounds are not mere
positional isomers of those disclosed and claimed in US 7,230,024. Although the structures below would be considered structural isomers, they are not positional isomers. Clearly, changing the orientation of the core is much more than just moving the point of attachment of a single substituent. If one compares the two Formula (111) structures below, one can easily see that access to the carbonyl is hindered in one of the structures but not in the other one. In both the Formula (111) and Formula (IV) structures, the closeness of the R^{3a} and R^{3b} substituents on one orientation would have more influence on the phenyl group than the other orientation. This could easily affect the binding of the compound to a receptor.



(III)

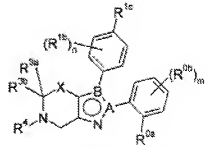


(III)



(IV)

Compounds of the present invention



(IV)

Compounds of US 7,230,024

In all of the compounds above, X is a bond, A is nitrogen and B is carbon.

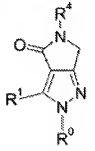
Response:-

The compounds are isomers. Appellants agree that they are structural isomers.

Yes the orientation changes however the position of the two phenyl ring s and the pyrazole remain the same.

The diagram shown above is misleading as X is a bond . The R1 and R0 phenyl remain on the same side.

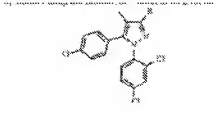
Table 1



Ex. No.	R^0	R^1	R^4	LCMS m/z (M+1)
1A-2	2-chlorophenyl	4-cyanophenyl	isopropyl	377.1
1A-3	2-chlorophenyl	4-chlorophenyl	isopropyl	386.1

See e

It is also on the same side as the known drug SR 141716.



Thus teaching that this may be the part of the compound that gives the activity.

Thus the motivation to try as the =O is in the part of the compound which may or may not effect the activity. There is definite amount of predictability of success.

Appellants further argue that

We elaborated on this requirement in the case of In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995), where we stated that "[n]ormally a prima facie case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound." That is so because close or established "[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds." Id~ A known compound may suggest its homolog, analog, or isomer because such compounds "often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." Id._~. We clarified, however, that in order find a prima facie case of unpatentability in such instances, ***a showing that the "prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention" was also required.*** Ido (citing In re Jones, 958 F.2d 247 (Fed Cir. 1992), 919 R.2d 688; Grabiak, 769 F.2d 729; In re Lalu, 747 F.2d 703 (Fed Cir. 1984)).

Response ;

The prior art along with the known SR 141716 clearly teaches the similarity in the structure is due to the pyrazole with the 2 phenyl ring, which is the same as in the US 7, 230,024 compounds also. This is a strong motivation and suggestion that making changes on the other end of the pyrazole would not affect the activity.

Appellants further argue that their reasoning is consistent with the legal principles enunciated in KSR. While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant filed to combine the elements in the way the claimed new invention does" in an obviousness determination. KSR, 127 S.Ct. at 1731.

Response :-

At the time of the invention SR 141716

Colombo, G., *et al.,* "Appetite Suppression and Weight Loss after the Cannabinoid Antagonist SR141716," Life Sci., 63, PL113-PL117 (1998); Simiand, J., *et al.,* "SR141716, a CB1 Cannabinoid Receptor Antagonist, Selectively Reduces Sweet Food Intake in Marmose," Behav. Pharmacol., 9, 179-181 (1998); (all reference are cited in a the specification, page 2.)

was a well known compound and applicants compounds have a similar structure. The difference is in the pyrazole ring. This provides enough motivation to modify the compounds of the US 7,230,024 at the C=O position and expect them to have the same properties.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Conclusion

Thus the claims 1, 4, 8, 9, 10, 31, 35, 36, 42, 43, 49, 55, 59 and 64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-23 of U.S. Patent No. 7, 230,024.

Respectfully submitted,

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